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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/973,139 | 10/09/2001 | Paul W. Rockley | 2730 | 4692 |

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EXAMINER

DAVIS, DANIEL J

ART UNIT PAPER NUMBER

3731

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,139

Applicant(s)

Rockley et al.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12, 17-19, 23-25, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 3-5, 26-28, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although applicants do not disclose that the first instrument is vibrated, and they do disclose a power line associated with the first instrument but not with the second, this is not sufficient to support that applicants had possession of "an unvibrated shaft" at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4, 26-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,154,696 to Shearing.

As illustrated in Fig. 4, Shearing discloses a first instrument having shaft 28, a tip 34, and an irrigation port "A". As illustrated, the instrument has a shaft with a lumen. The instrument also has a conduit for receiving irrigation fluid.

The second instrument 56 comprises a *sleeveless* shaft. The shaft is used for aspiration (Abstract) and hence inherently has a lumen. As the instrument aspirates, it inherently vibrates to some degree. The second instrument is inherently capable of fragmenting a cataract if sufficient force is applied to break the cataract. Col. 6, lines 24-28 disclose that the wound opening is less than about 2 mm.

Claims 3, 4, 26-28, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated Shearing, or in the alternative as being unpatentable over Shearing in view of *Bimanual micro-incision cataract surgery is the wave of the future*. Col. 1, line 66—col. 2, line 4 of Shearing disclose a device published in 1985. The device has first and second instruments. The first instrument has a shaft, an irrigation port, a lumen, and inherently has some sort of a conduit to receive the irrigation fluid.

The second instrument is sleeveless, ultrasonically vibrated, and used to aspirate. (Col. 1, lines 26-65 provide a backdrop for the second instrument being sleeveless and ultrasonically vibrated. Furthermore, *Bimanual micro-incision* also cites Shearing's published work in 1985 and supports this interpretation.) The wound incision is "approximately 1.5 mm."

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In the alternative, it would have been obvious to make the Shearing 1985 aspirating device sleeveless and ultrasonically vibrated as taught by *Bimanual micro-incision* in order to break up a cataract within an incision of 1.5 mm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shearing in view of U.S. Patent No. 5,562,640 to McCabe. Shearing fails to disclose "the first instrument comprising a plurality of irrigation ports." Nevertheless, McCabe teaches a plurality of irrigation ports 44 (Fig. 8; col. 5., lines 31—et seq.) to decrease fluid pressure. The McCabe device is intended to be used in the more general surgical art. However, since lens material is tissue, and cataract surgery is a subset of the more general surgical art, those in the cataract surgical art would be motivated to look for teachings in the more general surgical art that might be transferable. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of irrigation ports to decrease fluid pressure.

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Allowable Subject Matter

Claims 10-12, 17-19, 23-25, 29 and 30 are allowed. The following is examiner's reasons for allowable subject matter: The prior phacoemulsification art fails to disclose or suggest all of the limitations of the claims including the "first instrument having a shaft...and a tool tip extending transverse to said shaft..."

Response to Arguments

Applicants' arguments with respect to the rejections under 35 U.S.C. 103 over U.S. Patent no. 4,608,050 to Wright et al. in view of U.S. Patent No. 6,319,222 to Andrew et al. have been considered persuasive, but are moot in view of the new grounds of rejection.

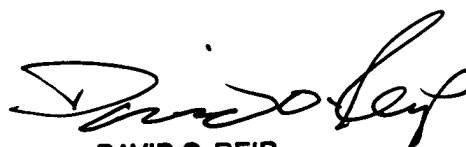
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD
June 24, 2004



DAVID O. REIP
PRIMARY EXAMINER